

### REMARKS

The disclosure is objected to because of informalities. The Related Applications paragraph has been amended to reflect the status of a related application and thereby overcomes this objection. Applicant respectfully requests that this objection be withdrawn.

Claims 1-114 have been canceled.

New method claims 115 to 120 are submitted for examination.

Claims 115 to 120 are pending in the application. Claim 115 is the sole independent method claim.

Regarding the previously submitted claims, the Examiner believes that the claims of various other patents and/or a pending application, considered in view of the teachings of Imran U.S. 5,156,151 (Imran '151) and Karlstrom et al., *Ectopic jejunal pacemakers and enterogastric reflux after Roux gastrectomy: Effect of intestinal pacing*, 1989 (the Karlstrom Article), render the invention obvious. This is an obviousness-type double patenting rejection.

The submission of new claims is intended to directly address the Examiner's position and thereby simplify and advance prosecution. New claim 115 defines a method that (i) deploys a catheter in association with tissue at or near a sphincter, the catheter carrying a mapping device; (ii) operates the mapping device to detect electrical events in the tissue; (iii) analyzes the detected electrical events; (iv) diagnoses dysfunction affecting the tissue based, at least in part, upon the analysis; (v) selects at least one target tissue treatment site based, at least in part, upon the analysis; (vi) deploys a catheter in association with the at least one target tissue treatment site, the catheter carrying a treating device; and (vii) operates the treating device to alter the detected electrical events and thereby treat the dysfunction. None of the documents cited by the Examiner teaches or suggests the subject matter of this claim.

The claims of various other patents and/or a pending application cited by the Examiner<sup>1</sup> are all directed to the ablation of tissue at or near a sphincter. None of these claims teach or suggest a method of events (as defined in new method claim 1125), which occur before treatment, including

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<sup>1</sup> / For the record, these are Claims 1-88 of U.S. Patent No. 6,056,744; Claims 1-51 of U.S. Patent No. 6,254,598; Claims 1-21 of U.S. Patent No. 6,258,087; Claims 1-16 of U.S. Patent No. 6,402,744; Claims 27-52 of U.S. Patent No. 6,077,257; Claims 1-9 of U.S. Patent No. 6,673,070; Claims 1-17 of U.S. Patent No. 6,613,047; Claims 1-90 of U.S. Patent No. 6,749,607; and claims pending in Serial No. 09/911,874

analyzing tissue at or near a sphincter and selecting at least one target tissue treatment site based, at least in part, upon the analysis. Imran '151 discloses a cardiac mapping and ablation device and a method of mapping and ablating cardiac tissue. There is nothing in Imran '151 that teaches or suggest or predicts (absent knowledge and appreciation of the invention defined in new claim 115), that tissue dysfunction at or near a sphincter can be analyzed by a catheter-based mapping device before treatment and at least one targeted tissue site can be selected for treatment based, at least in part, upon the analysis, to treat the dysfunction. The Karlstrom Article maps in the duodenum and/or jejunum after a treatment has occurred (see, e.g., The Karlstrom Article: Abstract -- "The aims of this study were to determine whether ectopic pacemakers are present in the Roux limb of dogs after vagotomy and Roux gastrectomy" (emphasis added) – ). There is nothing in the Karlson Article that teaches or suggests or predicts that mapping can be used at or near a sphincter before treatment to select a targeted treatment site for the treatment itself.

The Examiner's attention is directed to the claims of related, commonly owned US 6,006,755 and US 6,405,732 (listed in the attached Information Disclosure Statement) and allowed pending Application Serial No. 10/156,505 (Base Issue Fee Paid) (a copy of the allowed claims is attached) – which share the same priority date of the instant case. Applicant offers to file a Terminal Disclaimer based upon the claims of these related, commonly owned cases upon indication of allowability of claims 115 to 120.

Reconsideration in view of the foregoing amendments and remarks and allowance of claims 115 to 120 are respectfully requested.

Respectfully Submitted,

By

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**ALLOWED CLAIMS**

**(Serial No. 10/156,505)**

1. An apparatus comprising  
a treatment device including at least one of a mapping electrode or a treatment electrode,  
the treatment device being sized and configured for introduction into at least a portion of a  
tissue region comprising at least one of a sphincter, a lower esophageal sphincter, a stomach, a cardia  
or a fundus;

means for stimulating the tissue region to produce a transient relaxation of at least a portion  
of one of the sphincter, the lower esophageal sphincter, the stomach, the cardia or the fundus;

means coupled to the treatment device for identifying a portion of one of the sphincter, the  
lower esophageal sphincter, the stomach, the cardia or the fundus causing the transient relaxation;  
and

means coupled to the treatment device for delivering energy from the mapping electrode or  
the treatment electrode to treat the portion of one the sphincter, the lower esophageal sphincter, the  
stomach, the cardia or the fundus causing the transient relaxation.

2. The apparatus of claim 1  
wherein the means for stimulating includes one of an electrical stimulation, a mechanical  
stimulation, a stretch stimulation or a chemical stimulation.

3. The apparatus of claim 1, further comprising  
means for performing a post treatment stimulation on one of the sphincter, the lower  
esophageal sphincter, the stomach, the cardia or the fundus; and  
means for assessing an effectiveness of treatment in preventing the transient relaxation.

4. The apparatus of claim 1  
wherein the means for stimulating includes one of an external stimulation device or an  
internal stimulation device, wherein the external stimulation device is positionable on the skin near  
the stomach or wherein the internal stimulation device is positionable in the portion of one the  
sphincter, the lower esophageal sphincter, the stomach, the cardia or the fundus.

5. The apparatus of claim 88  
wherein the means for stimulating includes one of an internal stimulation or a transdermal stimulation.

6. An apparatus comprising  
a treatment device having at least one of a mapping electrode or a treatment electrode;  
the treatment device being sized and configured for introduction into at least a portion of a tissue region comprising at least one of a sphincter, a lower esophageal sphincter, a stomach, a cardia or a fundus;

means coupled to the treatment device for detecting an electrical activity causing a transient relaxation of at least a portion of the sphincter, the lower esophageal sphincter, the stomach, the cardia or the fundus;

means coupled to the treatment device for delivering energy to treat the electrical activity ;  
and

means coupled to the treatment device for mapping the tissue region after the treatment to assess the effectiveness of the treatment.

7. An apparatus comprising  
a treatment device having at least one of a mapping electrode or a treatment electrode, the treatment device being sized and configured for introduction into at least a portion of one of a sphincter, a lower esophageal sphincter, a stomach, a cardia or a fundus;

means for detecting a bioelectric activity causing a transient relaxation of at least a portion of the sphincter, the lower esophageal sphincter, the stomach, the cardia or the fundus;

means for delivering energy from the treatment delivery device to treat the bioelectric activity; the treatment device comprising

a basket assembly including a first and a second arm, the basket assembly being coupled to an elongated member and having a deployed and a non-deployed configuration;

an inflatable member coupled to the elongated member and positioned in an interior of the basket assembly, the inflatable member being coupled to an inflation lumen, the inflatable member having a deployed state and a non-deployed state, wherein in the deployed state the inflatable member expands the basket assembly to the basket assembly deployed configuration;

a first energy delivery device positionable in the first arm and advanceable from the first arm to a selected treatment site; and

a second energy delivery device positionable in the second arm and advanceable from the second arm to a selected treatment site;

at least one of the first and second energy delivery devices being adapted to deliver RF energy to a treatment site in one of the sphincter, the lower esophageal sphincter, the stomach, the cardia or the fundus to at least partially ablate one of a nerve pathway, an afferent pathway, a electrical pathway, a mechanoreceptor pathway or a chemoreceptor pathway.